K123955

MAR 0 8 2013

510(k) Summary

Summary of Safety and Effectiveness

Submitter Information - 21 CFR 807.92(a)(1):

Submitter: Life Technologies Corporation
5791 Van Allen Way
Carlsbad, CA 92008

Manufacturer: Life Technologies Holdings Pte Ltd
Blk 33, #07-06, Marsiling Industrial Estate, Road 3
Singapore 739256

Establishment Registration No: 3003673482

Contact: Deanna Vella, Regulatory Affairs Manager

Phone: 760-918-3000

Fax: 760-476-6934

E-mail: deanna.vella@lifetech.com

Alternate Contact: Nikki Arora, Engineer, Regulatory Affairs

Phone: 650-554-2268

Fax: 650-638-6786

E-mail: nikki.arora@lifetech.com

Date Prepared: December 20, 2012

Name of Device and Classification – 21 CFR 807.92(a)(2):

Product Name: QuantStudio™ Dx Real-Time PCR Instrument

Device Classification: Class II

Product Code: OOI, Real-Time Nucleic Acid Amplification System for Real Time Instruments.

Predicate Device – 21 CFR 807.92(a)(3):

Predicate: Abbott *m*2000™ System consisting of *m*2000*sp* and *m*2000*rt* instruments, K092705

Device Description – 21 CFR 807.92(a)(4):

The QuantStudio™ Dx Real-Time PCR Instrument is a bench top Real-Time PCR instrument that uses fluorescent-based polymerase chain reaction (PCR) reagents to provide qualitative or quantitative detection of target nucleic acid sequences (targets) using real-time analysis.

The QuantStudio™ Dx Real-Time PCR Instrument system includes the following components:

- QuantStudio™ Dx Real-Time PCR instrument with embedded graphical user interface (eGUI) Touchscreen
- Thermal Block, also referred to as the sample block, with associated Heated Cover and Plate Adaptor
- Calibration and verification materials for instrument qualification
- Computer workstation with a monitor, keyboard and mouse
- QuantStudio™ Dx instrument software

Intended Use/Indications for Use – 21 CFR 807.92(a)(5):

The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended to perform fluorescence-based PCR to provide detection of FDA cleared and approved nucleic acid sequences in human-derived specimens. The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended for in vitro diagnostic use by trained laboratory technologists in combination with nucleic acid reagent kits/tests manufactured and labeled for diagnostic purposes on this instrument.

Summary of technological characteristics of the device compared to the predicate devices– 21 CFR 807.92(a)(6):

The Life Technologies QuantStudio™ Dx Real-Time PCR Instrument ("Subject Device") and the legally marketed devices, Abbott *m*2000™ System ("Predicate Device") is described in the table below:

Predicates Comparison – Life Technologies QuantStudio™ Dx Real-Time PCR Instrument vs. Abbott *m*2000™ System

Item	**Subject Device** QuantStudio™ Dx Real-Time PCR Instrument	**Predicate Device** Abbott *m*2000™ System
Similarities		
510(k)	N/A	K092705
Regulation	862.2570 Instrumentation for clinical multiplex test systems.	Same
Product Code	OOI: Real-Time Nucleic Acid Amplification System for Real Time Instruments.	OOI: Real-Time Nucleic Acid Amplification System for Real Time Instruments.
Device Class	Class II	Same
Intended Use	The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended to perform fluorescence-based PCR to provide detection of FDA cleared and approved nucleic acid sequences in human-derived specimens. The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended for in vitro diagnostic use by trained laboratory technologists in combination with nucleic acid reagent kits/tests manufactured and labeled for diagnostic purposes on	The Abbott *m*2000™ System is intended for in vitro diagnostic use in performing FDA cleared and approved nucleic acid testing in clinical laboratories. It comprises the Abbott *m*2000*sp* and the Abbott *m*2000*rt* instruments. The Abbott *m*2000*sp* is an automated system for performing sample preparation for nucleic acid testing. The Abbott *m*2000*rt* is an automated system for performing fluorescence-based PCR to provide quantitative and qualitative detection of nucleic acid sequences.

Item	Subject Device QuantStudio™ Dx Real-Time PCR Instrument	Predicate Device Abbott *m*2000™ System
Similarities		
	this instrument.	
Technology/ Detection	Real-Time PCR	Same
Specimen Types	Nucleic acid	Same
Assay Format	Homogeneous, closed tube PCR	Same
Degree of Automation	Requires manual transfer of amplification mixture to amplification/detection instrument. Automated control of amplification, detection, and data analysis.	Same
Primary Operational Amplification and Detection Components	Integrated thermal cycler and microvolume fluorimeter for walk away PCR amplification and detection	Same
Heating Method for Amplification	Peltier device with sample block	Same
Detection Procedure	Optical detection of stimulated fluorescence	Same
Detection Chemistries	Fluorescence labeled target-specific probes	Same

Item	Subject Device QuantStudio™ Dx Real-Time PCR Instrument	Predicate Device Abbott *m*2000™ System
Differences		
Product Code	OOI: Real-Time Nucleic Acid Amplification System for Real Time Instruments.	OOI: Real-Time Nucleic Acid Amplification System for Real Time Instruments.
User Interface	PC with instrument-specific software. Instrument has touchscreen console.	PC with instrument-specific software
Amplification Reaction Volume	10-30 µL in 96-well Fast PCR plates	25-100 µL in 96-well PCR plates
Sample Preparation	No automated sample processing instrument offered in conjunction with the QuantStudio™ Dx Instrument.	Pairing with the *m*2000*sp* instrument provides automated sample processing.

Our analysis of the differences in user interface, amplification reaction volumes, and sample preparation between the Subject Device and the Predicate Device indicates that these differences do not impact performance or raise new/different questions of safety and effectiveness, and therefore render the Subject Device as Substantially Equivalent.

Special Control/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077819.htm

Performance Data – 21 CFR 807.92(b):

As noted in the Cover Letter in this 510(k), Quidel® Corporation will submit a traditional 510(k) for the Molecular Real-Time PCR Direct *C. Difficile* Tox A/B that will be used with the QuantStudio™ Dx Real-Time PCR Instrument. To that end, testing to demonstrate non-clinical performance of the QuantStudio™ Dx Real-Time PCR Instrument was led by Quidel® Corporation as part of a collaboration agreement between

the two companies. This section provides a brief summary of the non-clinical performance studies and conclusions that demonstrate instrument performance when testing the Quidel Molecular Real-Time PCR Direct *C. Difficile* Tox A/B.

Complete non-clinical performance data can be found in Quidel's Molecular Real-Time PCR Direct *C. Difficile* Tox A/B traditional 510(k) submission.

Non-Clinical Performance Data– 21 CFR 807.92(b)(1):

Analytical performance:

a. Precision/Reproducibility:

Precision: For the Precision/Within Laboratory Repeatability study, a blinded four-member panel consisting of *C. difficile* positive and negative sample was tested by two operators, twice a day using a single assay lot of Quidel Molecular Direct *C. difficile* Assay for twelve (12) days.

QuantStudio™ Dx Real-Time PCR Instrument				
C. difficile	5X LoD	2X LoD	0.3X LoD	Negative
% Detection	100%	100%	88%	0%
Average Ct	16.51	17.70	21.13	N/A
STDEV	0.42	0.76	1.37	N/A
%CV	2.6%	4.3%	6.5%	N/A

Reproducibility: In order to confirm the reproducibility of the Quidel Molecular Direct *C. difficile* Assay a blinded and randomized study panel containing *Clostridium difficile* negative and positive samples were tested at three (3) test sites, two of which were clinical sites. Each site tested a reproducibility panel and assay controls for five (5) days in triplicate on each instrument. The testing was done by two operators at each site. Each operator ran the panel once a day using one lot of Quidel Molecular Direct *C. difficile* Assay.

Reproducibility Results – QuantStudio™ Dx Instrument										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
High Negative 0.3x LoD	8/30	22.9	5.0	15/30	22.5	1.3	15/30	22.5	1.5	38/90
Low Positive 2x LoD	30/30	20.4	5.9	30/30	19.0	5.1	30/30	19.2	0.8	90/90
Med Positive 5x LoD	30/30	18.4	4.2	30/30	17.5	0.4	30/30	17.9	0.7	90/90
Negative Specimen	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
Negative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
Positive Control	30/30	15.7	0.6	30/30	15.7	0.1	30/30	15.5	0.1	90/90

b. Detection limit:

The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular Direct *C. difficile* Assay was determined on QuantStudio™ Dx instrument using quantified (CFU/mL) cultures of two *C. difficile* strains (ATCC BAA-1870 and ATCC BAA-1872) serially diluted in a negative fecal matrix. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive.

Instrument	Strain	
	ATCC BAA-1870 LoD (CFU per assay)	ATCC BAA-1872 LoD (CFU per assay)
QuantStudio™ Dx	4.2 E-01	4.0E-02

The final assay LoD is defined as the higher of the two strain concentrations where 95% positivity was observed. The final assay LoD is 4.2E-01 CFU/assay.

Clinical Performance Data– 21 CFR 807.92(b)(2):

Comparison studies:

a. Method comparison with predicate device:

Performance characteristics of the Quidel Molecular Direct *C. difficile* Assay were established during a prospective study conducted August to November 2012. Seven hundred and ninety-two (792) samples used for this study were collected from patients suspected of having *Clostridium difficile*-associated disease (CDAD) at four (4) distinct geographical sites across the United States. These specimens were tested with the Quidel Assay on the Life Technologies QuantStudio™ Dx Real-Time PCR Instrument at one of three (3) facilities.

Patient age and gender for the combined sites are presented below.

Combined Sites – Age and Gender Distribution				
Age	Gender		Total	Total prevalence of the Quidel Molecular Direct C. difficile Assay on the QuantStudio™ Dx Real-Time PCR Instrument
	Male	Female		
Unknown			2	50% (1/2)
≤ 2 years	5	5	10	10% (1/10)
2 to <12 years	28	21	49	24% (12/49)
12 to <18 years	10	14	24	21% (5/24)
18 to 21 years	6	7	13	8% (1/13)
>21 to 59 years	158	170	328	18% (60/328)
≥ 60 years	163	203	366	18% (65/366)
Total	370	420	792*	18% (145/792)

* includes two (2) patient samples with unknown age and gender.

Tissue Culture Cytotoxicity Assay Comparison

Seven hundred and ninety-two (792) samples were tested by both the Quidel Molecular Direct *C. difficile* Assay and the tissue culture cytotoxin assay. Three (3) specimens (0.4%) were indeterminate in the cytotoxin assay due to toxicity in the antitoxin well. One (1) specimen (0.1%) was invalid in the Quidel Molecular Direct *C. difficile* Assay

when initially tested. The specimen yielded a valid result (it was negative) when retested according to the Quidel Molecular Direct *C. difficile* Assay draft instructions for use. We elected to calculate clinical performance based on the initial test result obtained for each specimen. Therefore, the data below is for the remaining seven hundred and eighty-eight (788) specimens.

Combined Sites – Combined Ages								
	Tissue Culture Cytotoxin						**95% CI**	
Quidel Molecular Real-Time PCR Direct *C. difficile* Tox A/B Assay		**POS**	**NEG**	**Total**	**Sensitivity**	**93.3%**	**86.9%**	**96.7%**
	POS	**98**	**45***	**143**	**Specificity**	**93.4%**	**91.3%**	**95.0%**
	NEG	**7****	**638**	**645**				
	Total	**105**	**683**	**788**				

*Of the forty-five (45) discordant specimens (Quidel Molecular Positive/Tissue Culture Cytotoxin Negative) reported, forty-four (44) were tested with a FDA-cleared molecular device. Thirty-five (35) of these specimens were positive for *C. difficile*, and nine (9) were negative. The remaining specimen was unavailable for testing.

**Seven (7) discordant specimens (Quidel Negative/Tissue Culture Cytotoxin Positive) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were found positive for *C. difficile*, and five (5) were negative.

Enhanced Toxigenic Culture Comparison

Seven hundred and ninety-two (792) samples were tested by both the Quidel Molecular Direct *C. difficile* Assay and enhanced toxigenic culture. One (1) specimen (0.1%) was invalid in the Quidel Molecular Direct *C. difficile* Assay when initially tested. The specimen yielded a valid result (it was negative) when retested according to the Quidel Molecular Direct *C. difficile* Assay draft instructions for use. We elected to calculate clinical performance based on the initial test result obtained for each specimen. Therefore, the data below is for the remaining seven hundred and ninety-one (791) specimens.

Combined Sites – Combined Ages								
	Enhanced Toxigenic Culture						**95% CI**	
Quidel Molecular Direct *C. difficile* Assay		**POS**	**NEG**	**Total**	**Sensitivity**	**87.3%**	**81.1%**	**91.6%**
	POS	**137**	**8***	**145**	**Specificity**	**98.7%**	**97.5%**	**99.4%**
	NEG	**20****	**626**	**646**				
	Total	**157**	**634**	**791**				

*Eight (8) discordant specimens (Quidel Molecular Positive/Enhanced Toxigenic Culture Negative) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were positive for *C. difficile*, and six (6) were negative.
**Seventeen (17) out of twenty (20) discordant specimens (Quidel Negative/ Enhanced Toxigenic Culture Positive) reported, were tested with a FDA-cleared molecular device. Three (3) specimens were unavailable for testing. Eleven (11) of these specimens were found negative for *C. difficile*, and six (6) were positive.

Conclusion

This summary of safety and effectiveness information provides the necessary detail for a determination of substantial equivalence for the QuantStudio™ Dx Real-Time PCR Instrument.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Life Technologies
Deanna Vella
5791 Van Allen Way
Carlsbad, California 92008

Re: K123955
Trade/Device Name: Life Technologies
Regulation Number: 21 CFR §862.2570
Regulation Name: QuantStudio™ DX Real-Time PCR Instrument
Regulatory Class: Class II
Product Code: OOI
Dated: December 20, 2012
Received: December 21, 2012

Dear Ms. Vella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k123955

Device Name: QuantStudio™ Dx Real-Time PCR Instrument

Indications for Use:

The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended to perform fluorescence-based PCR to provide detection of FDA cleared and approved nucleic acid sequences in human-derived specimens. The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended for in vitro diagnostic use by trained laboratory technologists in combination with nucleic acid reagent kits/tests manufactured and labeled for diagnostic purposes on this instrument.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Center for Devices and Radiological Health

Raquel A. Peat -S
2013.03.07 10:30:27 -05'00'

Division Sign-Off
CDRH, Center for Devices and Radiological Health

510(k) K123955